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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,382	09/10/2001	Conor Mulrooney	3551P003	2902
7590	10/28/2004	EXAMINER		
Monique A Morneault Wallenstein & Wagner 53rd Floor 311 South Wacker Drive Chicago, IL 60606			WILDER, CYNTHIA B	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 10/28/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/936,382	MULROONEY ET AL.
	Examiner	Art Unit
	Cynthia B. Wilder, Ph.D.	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 12 July 2004.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-79 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-79 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date **1125/02**

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

1. Applicant's preliminary amendment filed on September 10, 2001 and December 13, 2001 has been entered and is acknowledged. Claims 1 -79 are pending.

### ***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on March 12, 1999. It is noted, however, that applicant has not filed a certified copy of the 9905580.8 application as required by 35 U.S.C. 119(b).

### ***Specification***

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.

- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-79 are vague and confusing in the independent claims because the claims are extensively wordy, thus making interpretation of Applicant's intent difficult. Likewise, there is no clear nexus between the different steps within the claimed methods which further makes interpreting the claims difficult. The claims appear to be a literal translation into English from a foreign document. It is suggested amending the claims to conform to current US practice by, e.g., inserting "wherein" clause in the dependent claims and etc.

(b) Claims 1-4, 6, 11-12 are indefinite and confusing for the limitations (numbers) in parentheses because it cannot be determined if the limitations in parentheses are a part of the claims and if so, what the limitations are in reference to or if the limitations are a separate entity.

Clarification is required.

(c) Claims 1-79 are indefinite at the recitation of "capable of" in claims 1, 3, 5, 11, 12 because it cannot be determine if the limitation after the "capable of" language is a property of the "polymerizing agent" or "separating agent" or a separate step. It is suggested changing "capable of extending" or "capable of removing" to "which extends" or "which removes" or some other language as supported by the specification as originally filed..

(c) Claims 2 and 4 lacks antecedent bases for "the removal of said extension nucleic acid" because the claim 1 from which is depends does not recite an active step of "removing any extension nucleic acid". Likewise, the claim 2 is wordy, vague and confusing overall. For example, it is unclear Applicant's intent at "against whose activity.... is/are protected".

***Prior Art***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lane et al. (WO 98/02580, 01/22/1998) teach a method for detecting the presence or absence of analyte in a sample comprising: (a) contacting the sample with a first reagent having a first portion which specifically binds to the analyte and a second portion comprising a polynucleotide sequence, such that complex of the analyte and the first reagent is formed; (b) contacting the complex of the analyte and the first reagent with an amplifying entity having a first polynucleotide sequence and a second polynucleotide sequence wherein the first polynucleotide sequence is complementary to the polynucleotide sequence of the second portion of the first reagent, such that a complex of the analyte, the first reagent and the amplifying entity is formed; (c) contacting the complex of the analyte, the first reagent and the amplifying entity with a second reagent, the second reagent having a first portion which includes a polynucleotide sequence complementary to the second polynucleotide sequence of the amplifying entity and a

second portion to form an extendable complex of the analyte, the first reagent, the amplifying entity and the second reagent; (d) contacting the extendable complex with an extension reagent, the extension reagent binds to the extendable complex to form a complex of the analyte, the first reagent, the amplifying entity, and the extension reagent and (e) contacting the complex of the analyte, the first reagent, the amplifying entity and the extension reagent with a plurality of signaling moieties, each of the signal moieties comprising a detectable label and a polynucleotide sequence complementary to the polynucleotide sequence of the extension reagent to form a detectable complex of the analyte, the reagent, the amplifying polynucleotide, the extension reagent and the signaling moieties; and (f) detecting the label as indicative of the presence or absence of analyte in the sample (see page 26, lines 9-36).

The reference differs from the instant invention in that Lane et al does not teach a polymerizing agent capable of extending the 3' terminus of the amplifying entity of any of the preceding steps by synthesizing a complementary strand to an extension nucleic acid sequence. Lane et al also do not teach a separating agent capable of removing extension nucleic acid sequences and reagents and conditions necessary to effect the action of the polymerizing agent and separating agent to allow the extension of the 3' terminus of the amplification nucleic acid sequence of any of the preceding step by the synthesis of a plurality of sequences complementary to the extension nucleic acid sequence and detecting any bound amplification template from an amplification step or steps and correlating the results of detection with the presence of the target molecule.

***Conclusion***

5. No claims are allowed. However, the claims are free of the prior art. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to [cynthia.wilder@uspto.gov](mailto:cynthia.wilder@uspto.gov). Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

*Cynthia Wilder*

CYNTHIA WILDER  
PATENT EXAMINER

10/26/04